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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,592	07/20/2001	Jonathan M. Friedman	389004/039 JJD/BO	1403

7590 08/27/2004

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EXAMINER	
LY, CHEYNE D	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 08/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/910,592	FRIEDMAN, JONATHAN M.	
	Examiner	Art Unit	
	Cheyne D Ly	1631	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *August 11, 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☒ The proposed amendment(s) will not be entered because:

(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☒ they raise the issue of new matter (see Note below);

(c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *See Continuation Sheet*.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *1-12,14-23,37,39-53,61 and 62*.

Claim(s) withdrawn from consideration: *13 and 63-69*.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☒ Other: *See Continuation Sheet*

Continuation of 2. NOTE:
Applicant's proposal to replace the term "becomes" in step (e), line 4, with the phrase "can be converted into" raises a new issue that would require further consideration and/or search. For example, the previous limitation of "becomes" has been reasonably construed as an active step, whereas the limitation of "can be converted into" is only a statement of capability which is different from the previously recited limitation of "becomes."

The proposed amendment to step (g) of claims 1 and 48 raises the issue of new matter. The proposed deletion of the limitation of "any one...presumed values" raises the issue of new matter because the pointed to support (page 23, lines 8-11) only cites "presumed values", however, not the practice of step (g), last 2 lines, without any "presumed values" limitation.

Therefore, the proposed claim amendments, filed August 11, 2004, has not been entered.

Continuation of 5. does NOT place the application in condition for allowance because:

Claims 1-12, 14-23, 37, 39-53, 61, and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained with respect to claims 1-12, 14-23, 37, 39-53, 61, and 62, as recited in the previous office action mailed February 11, 2004, because of the non-entry of the proposed claim amendments as discussed above.

Claims 1-12, 14, 16-23, 37, 39-45, 47-53, 61, and 62 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This new matter rejection is maintained with respect to claims 1-12, 14-23, 37, 39-53, 61, and 62, as recited in the previous office action mailed February 11, 2004, because of the non-entry of the proposed claim amendments as discussed above.

Claims 1-12, 14, 16-23, 37, 39-45, 47-53, 61, and 62 are rejected under 35 U.S.C. 112, first paragraph.

This rejection is maintained with respect to claims 1-12, 14-23, 37, 39-53, 61, and 62, as recited in the previous office action mailed February 11, 2004.

Applicant argues that no undue experimentation would be required to apply Applicant's claimed method to other crystals because there are thousands of electron density maps in the structural biological community. Further, Applicant argues that the claimed invention is applicable to all x-ray data available today and available tomorrow. Applicant's argument has been fully considered and found to be unpersuasive.

The basis for the instant lack of enablement in scope rejection is that the claimed method "determine[s] the three-dimensional structure of a molecule of interest from experimental X-ray diffraction data for a crystal of said molecule of interest." As documented by the citation of Drenth and New Focus, protein crystallization is in essence a trial-and-error method, and the results (X-ray diffraction data) are usually unpredictable. Therefore, a method that relies on data from an unpredictable art such as protein crystallization would require clear and precise guidance for one skilled in the art to reliably use said method. Applicant has disclosed information to enable one skilled in the art to use the claimed method specific for determining the three-dimensional structure of a Staphylococcal aureus nuclease (Page 33, lines 21-25). The instant specification does not provide sufficient disclosure to one of skill in the art to make and use the invention commensurate in scope with the instant claims. Due to the claimed method being directed to subject matter that is well supported in the art as being unpredictable, one skilled in the art would require undue experimentation to use the information disclosed for one specific crystal to practice the claimed invention on any other of predictable quality.

Applicant cites "The Cohen-Boyer patents" to support Applicant's argument above. It is noted that each application is examined based on its own fact pattern. Further, the basis for the instant rejection is that the claimed method is directed to subject matter that is well supported in the art as being unpredictable.

Claims 1-12, 14-23, 37, 39-53, 61, and 62 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Friedman (January 1999).

This rejection is maintained with respect to claims 1-12, 14-23, 37, 39-53, 61, and 62, as recited in the previous office action mailed February 11, 2004.

Applicant argues that Friedman does not anticipate the claimed invention because Friedman does not disclose every limitation of the proposed amended claims, filed August 11, 2004. Applicant's argument has been fully considered and found to be unpersuasive due to the non-entry the proposed claim amendments. Therefore, the instant rejection has been maintained as previously set forth in the Office Action, mailed February 11, 2004.

Continuation of 10. Other: The cancellation of claims 13 and 63-69 has not been entered due to the non-entry of the proposed claim amendments discussed above.

Ardin H. Marschel 8/25/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER